UNITED STATES DISCTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

ARIAD PHARMACEUTICALS, INC., MASSACHUSETTS INSTITUTE OF TECHNOLOGY, THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH, and THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE	)	Civil Action No. 02 CV 11280 RWZ
Plaintiffs,	)	U.S. District Judge Rya W. Zobel
v.	)	
ELI LILLY AND COMPANY,	)	
Defendant.	)	

DEFENDANT ELI LILLY AND COMPANY'S BENCH MEMORANDUM REGARDING DIRECT VERSUS INDIRECT INFRINGEMENT

Plaintiffs' bench memorandum on indirect infringement misstates the law and mischaracterizes Lilly's positions in this litigation. In order to clarify the state of the law and assist the Court with the distinctions between, and elements of, the various types of infringement contemplated under the patent laws, Defendant Eli Lilly and Company offers its bench memorandum.

Under the patent statute, 35 U.S.C. § 271, there are two types of infringement: direct under § 271(a) and indirect, or vicarious infringement under § 271(b) and (c). Indirect infringement is further divided into infringement by inducement (§ 271(b)) and contributory infringement (§ 271(c)). A prerequisite to a finding of either induced or contributory infringement is the necessary act of direct infringement; absent direct infringement there can be no indirect infringement. *See, e.g., Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336 (1961); *Standard*

Havens Products, Inc. v. Gencor Industries, Inc., 953 F.2d 1360, 1374 (Fed. Cir. 1991); *C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 673 (Fed. Cir. 1990); *Moleculon Research Corp. v. CBS, Inc.*, 872 F.2d 407 (Fed. Cir. 1989); *Preemption Devices, Inc. v. Minnesota Mining & Mfg. Co.*, 803 F.2d 1170, 1173 (Fed. Cir. 1986); *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986).

Plaintiffs do not dispute this requirement. Pl. Memo. at 1. Plaintiffs also do not dispute that Lilly is not a direct infringer. Thus, for liability for infringement to attach, Plaintiffs must prove that patients, when they take Evista® or Xigris®, directly infringe by performing the methods required by the patent claims, and that Lilly either contributes to or induces that infringement. Plaintiffs concur. *See, e.g,* Pl. Trial Brief at 3 ("the directly infringing acts are the use of Evista® and Xigris® by patients and doctors").

It also is Plaintiffs' burden to prove the acts of direct infringement that serve as a necessary prerequisite to any finding of indirect infringement by Lilly, and they acknowledge this burden. Pl. Trial Brief at 3.

The area of disagreement between the parties, therefore, is what legally must be shown to prove contributory or induced infringement.

DIRECT INFRINGEMENT

Under Section 271(a), liability for direct infringement arises when one:

> without authority, makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor....

35 U.S.C. § 271(a). The claims-at-issue in this suit are method claims directed to methods of reducing NF-kB activity. CITE CLAIM CONSTRUCTION ORDER?. Direct infringement of

method claims requires that the infringing party perform each and every step of the claimed method. *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1273 (Fed. Cir. 2004).

In this case, the Plaintiffs must prove what acts constitute acts of direct infringement. Specifically, while the Plaintiffs essentially argue that any use of Evista® or Xigris® in a patient according to the FDA-approved product label constitutes direct infringement, they must prove that the end result for any particular administration or category of administrations was (1) a reduction of NF-kB activity ***and*** (2) a reduction of certain NF-kB-mediated effects.[1] In addition to offering evidence at trial that Evista® and Xigris® do not reduce NF-κB activity or NF-κB-mediated effects, or both, Lilly will offer particular evidence that they do not do so (even assuming *arguendo*, that Evista® and Xigris® are capable of reducing NF-kB activity) in substantial populations of Evista® and Xigris® patients.

INDIRECT INFRINGEMENT

Unlike direct infringement, indirect or vicarious infringement contains an intent or knowledge requirement. As mentioned, indirect infringement also requires proof of direct infringement. Lilly has presented the separate elements of each of the indirect types of infringement below.

A. Contributory Infringement

Section 271(c) details the standard for contributory infringement:

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a **material part of the invention knowing the same to be especially made or especially adapted for use in an infringement** of

[1] These include either NF-kB-mediated effects of external influences (claim 80), NF-kB-mediated gene expression (claim 95), or bacterial lipopolysaccharide-induced expression of cytokines (claims 144 and 145). Claims 80 and 145 also require a reduction in binding of NF-kB to NF-kB recognition sites on genes that are regulated by NF-kB.

> such patent, and **not a staple article or commodity of commerce suitable for substantial non-infringing use**, shall be liable as a contributory infringer.

35 U.S.C. § 271 (c) (emphasis added). Plaintiffs and Lilly have little disagreement about how the case law on contributory infringement has developed.

Section 271(1) (c) itself sets forth the elements for proving contributory infringement. Plaintiffs must show each of the following:

> a) That Evista® and Xigris® are a material part of the claimed methods;
>
> b) That Lilly sold Evista® and Xigris® knowing that they were especially made or adapted for use in the claimed methods;
>
> c) That Evista® and Xigris® are not staple articles of commerce suitable for any substantial noninfringing use.

See 35 U.S.C. §271(c); *Dynacore*, 363 F.3d at 1275, *citing Sony Corp. of Am. V. Universal City Studios, Inc.*, 464 U.S. 417, 456 (1984). *Cross Medical Products, Inc. v. Medtronics Sofamor,* 424 F.3d 1293, 1312 (Fed. Cir. 2005).

B. Infringement by Inducement

Section 271(b) defines the act of inducement:

> Whoever **actively induces** infringement of a patent shall be liable as an infringer.

35 U.S.C. § 271 (b) (emphasis added).

To establish inducement, a patentee must prove that (1) there has been direct infringement and (2) " 'the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement.' " *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed. Cir. 2005) (quoting *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002)). Thus Lilly cannot simply intend to encourage conduct that ***may*** infringe in some patients, ***and may not*** infringe in other

patients. Lilly must specifically intend to encourage conduct that does in fact infringe. "Although not express in the statute [271(b)] requires proof of intent to induce infringement." *Metabolite Labs., Inc. v. Lab. Corp. of America Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004), *citing Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990).

"The mere sale of a product capable of substantial noninfringing uses does not constitute indirect infringement of a patent." *Dynacore*, 363 F.3d at 1274. In addition to the sale of that product, Plaintiffs must show that Lilly took active steps to encourage direct infringement:

> Though this court has never answered the question definitively, district courts have had occasion to consider "whether [a] defendants' lawful steps to sell [lawful products], which in turn will provide [their customers] access to the [lawful] product for both infringing and noninfringing uses, constitutes inducement of infringement. *** In other words, "sale of a lawful product by lawful means, with the knowledge that an unaffiliated, third party may infringe, cannot, in and of itself, constitute inducement of infringement.' *Organon, 244 F. Supp. 2d at 380*. We agree with this view of inducement.

Id. at 1276 n.6. Thus, encouraging someone to take a pharmaceutical product, even with the knowledge that such an unaffiliated third party ***may*** infringe, does not constitute inducement. The question, therefore, is whether the Lilly encourages conduct that ***does*** infringe.

Certainly, if no substantial noninfringing use is present, and plaintiffs can show that all patients taking these accused products would necessarily infringe, the mere sale of these products with instructions for use would constitute inducement. ***Where, however, a substantial number of patients do not infringe, Plaintiffs must establish that Lilly specifically instructed or encouraged the group that does infringe to take the products in a way that infringes.***

The *Dynacore* case is directly on point. In *Dynacore*, the Federal Circuit found that the mere sale of computer networks (LANs) that could be used in some instances by customers in a way that would infringe, but could also be used in other ways as well that would not infringe,

does not constitute inducement of infringement. Dynacore, the plaintiff, had tried to establish that the LANs would directly infringe when used according to a particular IEEE 1394 standard. By comparison, Plaintiffs here are trying to establish that the administration of Lilly's products would directly infringe when used according to Lilly's label.

The Federal Circuit explicitly set forth the standard that Plaintiffs must meet to prove infringement by inducement:

> Dynacore must therefore either demonstrate that LANs compliant with the IEEE 1394 Standard necessarily infringe the '732 Patent, ***or*** point to a specific instance of direct infringement and restrict its suit to liability stemming from that specific instance. We must therefore determine whether all LANs compliant with the IEEE 1394 Standard directly infringe the '732 Patent, or whether there may also be substantial noninfringing configurations of IEEE 1394 compliant net-works. We do not reach the defendant's liability under § 271(b) or (c) if there are substantial noninfringing uses of the defendants' products and there is no evidence of active and willful inducement.

(citations omitted) (emphasis added). *Id.* at 1275-1276.

Thus, to prove inducement, Plaintiffs here must prove either (1) that ***all*** patients complying with the product label would necessarily infringe the asserted claims of the '516 patent, ***or*** (2) that Lilly specifically instructed or encouraged particular patients or a particular group of patients to take the product in such a manner that directly infringe. In that case, any liability of Lilly for infringement would be limited to the infringing group of patients whose infringement was specifically encouraged or instructed by Lilly.

Plaintiffs have misstated the holding of *Dynacore* by categorizing the Court's decision on inducement as *dicta*, and this argument indicates their own confusion over how proof of indirect infringement requires direct infringement and how these standards are intertwined.[2] Contrary to

[2] The language cited by Plaintiffs ("***Dynacore*** therefore cannot even reach the question of the defendants' vicarious liability for indirect infringement") (emphasis added) was merely an

Plaintiffs' assertion, the *Dynacore* court ***expressly held*** that there was no infringement by inducement because the patentee had failed to establish that the underlying acts of direct infringement necessarily occurred when used according to the IEEE 1394 standard. *Id.* at 1277 ("We hold that the defendants…are not vicariously liable for indirect infringement…under either § 271(b) or § 271(c)"). This is not *dicta*. Furthermore, the plaintiff did not present any evidence of inducement under the second standard set forth by the Federal Circuit in *Dynacore* – that when conduct encouraged by defendants does not necessarily infringe, plaintiffs must point to specific instances of direct infringement and restrict their suit to liability stemming from encouragement of those specific instances.

The same is true here. To the extent that Plaintiffs cannot show that direct infringement necessarily occurs in all patients when Lilly's products are administered according to the product label, Plaintiffs must show that Lilly specifically instructed the group that does infringe to take the drugs in an infringing manner.

Plaintiffs also mischaracterize Lilly's position with respect to *Dynacore*. First, Plaintiffs suggest that Lilly has argued that Plaintiffs must provide direct evidence of direct infringement. Pl. Memo. at 3. Lilly has never suggested this is the case; direct evidence is certainly not required. Lilly only contends that Plaintiffs have the burden of proving direct infringement, which in turn means that Plaintiffs must present ***sufficient*** evidence of infringement, whether direct or circumstantial.

The cases Plaintiffs cite in support of their own "evidence" of direct infringement are factually distinguishable and provide further evidence of the difficulties in assessing direct

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indication by the court that the ***patentee*** had failed to establish an element of a claim of inducement, *i.e.*, the requisite act of direct infringement, rather than the ***Court*** not reaching the issue.

infringement in this case. Plaintiffs specifically quote the *Aventis* case for the proposition that a doctor's reliance on label information in prescribing a medication is evidence of direct infringement. Pl. Memo. at 3 (citing *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 411 F.Supp.2d 490, 517 (D.N.J. 2006). However, Plaintiffs have taken the case quote out of context, and cannot extrapolate the facts of *Aventis* to this case. *Aventis* is a preliminary injunction case. The *Aventis* court did not find that there was inducement, but merely that the patentee had established a likelihood of success in showing inducement. *Aventis Pharms.*, 411 F.Supp.2d at 517. In *Aventis*, three patents were at issue with claims directed to methods of (1) treating histamine-mediated conditions, by (2) administration of a compound called fexofenadine. *Id.* at 515. The alleged direct infringers were therefore doctors. *Id.* at 516-517. In *Aventis*, the alleged acts of direct infringement were the actual acts described on the product label. In addition in *Aventis*, the FDA had sent the alleged infringer a letter indicating its expectation that physicians would rely on the label information in making their decision regarding whether to treat patients with fexofenadine. *Id.* at 516. In stark contrast, as the Court is aware, in this case the claims are directed to methods of reducing NF-kB activity, and the only direct infringers are patients. *Aventis* is simply not comparable to this case, nor instructive on how to assess indirect infringement claims for this case.[3]

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[3] The remaining cases cited by Plaintiffs are similarly either misrepresented or inapplicable. The *Linear* case does not hold that any particular evidence is sufficient to prove indirect infringement; instead, *Linear* merely indicated that the patentee had raised sufficient issues to preclude summary judgment of non-infringement. *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1325-1327 (Fed. Cir. 2004). In *Mickowski*, while the court did find sales literature and instruction manuals sufficient evidence of inducement, it was because the documents "[taught] the patented method." *Mickowski v. Visi-Trak Corp.*, 36 F.Supp.2d 171, 180 (S.D.N.Y. 1999). *Moleculon* involved patent claims directed to methods of solving a puzzle, and the literature cited by the patentee specifically instructed users how to solve the puzzle. *Moleculon Res. Corp. v. CBS, Inc.*, 793 F.2d 1261 (Fed. Cir. 1986).

Second, Plaintiffs contend that Lilly is attempting to create a "substantial non-infringing use defense to inducement." Pl. Memo. at 4. In doing so, Plaintiffs improperly attempt to shift the infringement burden to Lilly to prove non-infringement. ("...even if Lilly could prove that a subset of women take Evista do not use the infringing method...."). Once again, Lilly has simply maintained that it is Plaintiffs' burden to prove direct infringement, not Lilly's burden to prove non-infringement. Specifically, Plaintiffs must prove which patients that take Evista® and or Xigris® have their NF-kB activity reduced, if any.

Plaintiffs further contend that even if there is such a defense, it is merely a damages issue rather than an infringement issue. Pl. Memo. at 4. However, the reason substantial non-infringing uses result in a reduction in damages is because Plaintiffs are not entitled to damages for non-infringing uses.[4]

In summary, *Dynacore* is factually and legally the most relevant to the case at hand. *Dynacore Holdings Corp. v. U.S. Philips Corp*, 363 F.3d 1263 (Fed. Cir. 2004). In *Dynacore*, the court provided a comprehensive analysis of the underlying act of direct infringement for the purpose of proving inducement. The patentee attempted to allege infringement by all sales based on evidence of one particular LAN configuration. *Id.* at 1274. In upholding summary judgment of non-infringement, the court rejected Dynacore's approach:

> This argument conflates two distinct requirements for establishing vicarious liability for indirect infringement. A defendant's liability for indirect infringement must relate to the identified instances of direct infringement. Plaintiffs who identify individual acts of direct infringement must restrict their theories of vicarious liability—and tie their claims for damages or injunctive relief—to the identified act...Plaintiffs who identify an entire category of infringers (*e.g.* the defendant's customers) may cast their theories of vicarious

[4] The *Insituform* case cited by Plaintiffs addressed whether "the district court correctly determined the extent to which defendants...instructed their licensees to use infringing Process 1 [as opposed to non-infringing Process 2], ***thereby inducing infringement***...." *Insituform Tech., Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1378 (Fed. Cir. 2004) (emphasis added).

> liability more broadly, and may consequently seek damages or injunctions across the entire category.

Id. In either case, the patentee must prove the direct infringement, either the specified instances or as a necessary rule for the category. *Id.* ("Dynacore must therefore either demonstrate that [a category of LANs] necessarily infringe…or point to a specific instance of direct infringement and restrict its suit to liability stemming from that specific instance.").

Therefore, in this case, to prove inducement, Plaintiffs must demonstrate

1. That ***all*** patients infringe, and that defendant intended the drugs to be used as labeled; or
2. If a substantial number of patients do not infringe, that defendants specifically instructed the group that does infringe to take the drugs in an infringing manner.

Lilly will offer final jury instructions consistent with the case law as set forth above. Should the Court wish any further elaboration on this issue, Lilly will be happy to respond.

Respectfully submitted,

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